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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER	
GAMBEL, P	
ART UNIT	**PAPER NUMBER**
1644	30

DATE MAILED: 09/21/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6/15/01

☑ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 71-73, 75-78, 80-82, 99 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 71-73, 75-78, 80-82, 99 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Applicant's amendment, filed 6/15/01 (Paper No. 29), has been entered.
Claim 80 has been amended.

Claims 71-73, 75-78, 80-82 and 99 are pending and being acted upon presently

Claims 1-70, 74, 79, 83-98 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 6/13/01 (Paper No. 29).
The rejections of record can be found in the previous Office Action (Paper No. 28).

3. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see the form PTO-948 previously sent in Paper No. 6.

Applicant will submit formal drawings upon the indication of allowable subject matter.

4. Upon reconsideration of applicant's amended claims, filed 6/13/01 (Paper No. 29), the previous rejection under 35 U.S.C. 112, first paragraph, scope with respect to claims 80-82 have been withdrawn.

5. Upon reconsideration of applicant's provision of the commercial availability of the RR1/1 antibody (see Attachment A), filed 6/13/01 (Paper No. 29), the previous rejection under 35 U.S.C. 112, first paragraph, for the deposit of the biological material RR1/1 has been withdrawn.

7. Claims 71-73, 75-78, 80-82 and 99 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Tomassini (PhD Dissertation, 1986; of record) for the reasons of record.
Tomassini teaches the isolation and characterization of the human rhinovirus receptor, including various cell and membrane preparations (see entire document).

8. Claims 71-73, 75-78, 80-81 and 99 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Tomassini et al. (J. Virol. 58: 290-295, 1986; of record)for the reasons of record.
Tomassini teaches the isolation characterization of the human rhinovirus receptor, including cellular and membrane preparations (see entire document).

9. Claims 71-73, 75-78, 80-81 and 99 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Colonno et al. (Virus Attachment and Entry into Cells, Proceedings of an ASM Conference held in Philadelphia, PA, April 10-13, 1985).

Colonno et al. Teach the characterization of the cellular receptor specific for attachment of most human rhinovirus serotypes, including cellular and membrane preparations (see entire document, including pages 112-115).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced rhinovirus receptor.

The products of the instant claims and the prior art are defined in terms of physical characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Also, it is noted that differences or variations were known in the art at the time the invention was made when protein molecular weight was determined by different methods and conditions.

The burden is on the applicant to establish a patentable distinction between the claimed and referenced products. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

10. Claims 71-73, 75-78, 80-81 and 99 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomassini (PhD Dissertation, 1986; of record) AND/OR Tomassini et al. (J. Virol. 58: 290-295, 1986; of record) AND/OR Colonno et al. (Virus Attachment and Entry into Cells, Proceedings of an ASM Conference held in Philadelphia, PA, April 10-13, 1985) OR Tomassini (PhD Dissertation, 1986; of record) in view of the art known use of artificial membranes for a variety of uses in protein chemistry at the time the invention was made and to isolate and produce functional active proteins.

Tomassini (PhD Dissertation, 1986), Tomassini et al. (J. Virol., 1986) and Colonno et al. (Virus Attachment and Entry into Cells) are all taught above.

These references do not teach the use of artificial lipid membranes per se.

However, providing proteins of interest in artificial lipid membranes in a variety of means for a variety of purposes for the characterization and determination of the structure-function of a protein of interest was well known and practiced at the time the invention was made.

Also, it is noted that "artificial lipid membranes" has broad meaning; given the prosecution of the instant application and applicant's assertion that is irrelevant whether HRRP or ICAM-1 when associated with detergents meets the claimed limitation of artificial lipid membranes (see applicant's amendment filed 2/4/00; Paper No. 20; page 6).

It is noted the prior art teaches the isolation and characterization of the rhinovirus receptor which reads on the claimed ICAM-1 preparations.

Given applicant's arguments that the prior art isolated prior art rhinovirus receptor may not have the properties of binding LFA-1/Mac-1/p150,95; it is noted that prior art rhinovirus receptor is clearly identified as being the receptor for rhinovirus receptor.

Given this clear teaching and the clear motivation of the ordinary artisan to characterize this protein further, as taught by the each reference; the ordinary artisan would have been able to isolate and characterize the HRV receptor with the known and desired functional properties, such as HRV binding.

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144.

Although the prior art may not known that the HRV receptor also had the ability to bind to LFA-1/Mac-1/p150,95; these adhesion molecule properties would have been expected properties given the isolation of a functional HRV receptor with ability to bind HRV.

One of ordinary skill in the art at the time the invention was made would have been motivated to isolate and characterize the structure-function nature of the HRV receptor, including the art known use of artificial lipid membranes; given its clear importance in rhinovirus attachment and infection. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Applicant's arguments in conjunction with the Rothlein Declaration under 37 CFR 1.132, 10/12/00 (Paper No. filed6/15/01 (Paper No. 29), have been fully considered but not found convincing.

Applicant argues in conjunction with the Rothlein Declaration that the Tomassini purified HRRP is not able to bind HRV (e.g. see page 46 of the Tomassini PhD Thesis).

Applicant's arguments, filed 6/15/01 (Paper No. 29), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same as of record..

Applicant argues in conjunction with In re Donohue, MPEP 2131, and Current Protocols in Protein Science as well as with the Rothlein Declaration under 37 CFR 1.132, 10/12/00 (Paper No. filed 6/15/01 (Paper No. 29),, that each and every element of the claims must be found in the cited references.

It is noted that any disruption in structure from the purification procedure leading to the elimination of HRV binding would also reduce or eliminate LFA-1 binding.

Applicant asserts that the Tommassini thesis and article teach the isolation and characterization of an inactive form of ICAM-1, which is incapable of binding to HRV, LFA-1, Mac-1 and p150,95.

Applicant submit that Colonno et al. show a predominant protein band migrating with an apparent molecular weight of 90,000, however further analysis of this candidate receptor protein is in progress as well as mentioning the Tommassini article.

In contrast, applicant asserts that applicant's purification procedure taught in the specification enables the isolation of a functional HRRP receptor (ICAM-1), capable of binding to HRV, LFA-1, Mac-1 and p150,95.

Applicant states that it is generally known in the art that activity of an isolated and purified protein depends primarily on the purification procedure use, the claimed functional limitation cannot be inherent properties of the reference rhinovirus receptor.

While it is acknowledged that isolation and purification of an active form of a membrane-associated protein is dependent on the purification procedure used; it was certainly within the purview of the ordinary artisan to isolate and purify functional forms of a known at the time the invention was made, given the arsenal of isolation and purification methods known and practiced at the time the invention was made. The use of detergents and other reagents suitable for chemical or biochemical characterization of a protein of interest did not proven the ordinary artisan to isolate the same protein and maintain its function by alternative methods. Here, too, the prior art does teach the isolation and characterization of the HRV receptor, its structural and functional properties, including its binding properties as well as antibodies thereto, wherein said antibodies bind the HRV receptor and block function.

In response to applicant's comments about other techniques to isolate proteins of interest available to the ordinary artisan at the time the invention was made; Williams et al. disclose the art known purification of glycoproteins antigens by affinity chromatography at the time the invention was made (in Weir et al. (Eds.) Handbook of Experimental Immunology, Volume 1: Immunochemistry Fourth Edition, Blackwell Scientific Publications, Oxford 1986; pages 22.1-~~22.4~~ 22.24).

Applicant's comments on the legal decisions are acknowledged; however, they are deemed appropriate for the rejections of record.

In contrast to applicant's assertions, the following of record is reiterated for applicant's convenience

Again, it is noted that in characterizing the HRV receptor, Tomassini et al. teach the isolation of the cellular receptors can be achieved by several methods, including but not limited to detergent treatment (page 113). Tomassini et al. clearly teach that the vast number of HRV serotypes use this HRV receptor for attachment, as determined by competition and functional assays (page 113).

While the thesis indicates that repeated attempts to use radiolabeled HRV in place of receptor antibody in the RIA gave inconclusive results owing to poor virus binding; it is not clear the conditions of the assay or the functional attributes of the radiolabeled receptor, since the data or details are not provided (page 44, paragraph 1).

However, immunoaffinity purification did further purify the HRV receptor, wherein said HRV receptor was bound by specific antibody, wherein said anti-HRV antibody could block HRV attachment and that the HRV receptor could be used as an immunogen to generate antisera which selectively inhibit HRV attachment to susceptible cells tested by both membrane binding and cell protection assays (pages 50-69).

Therefore, the thesis clearly states that the HRV receptor is utilized by the major groups of HRVs during attachment to cells (page 65, and Discussion on pages 107-118). Additional biochemical studies (pages 69-83) as well as initial cloning of the HRV receptor (pages 83-105) are also disclosed.

Further, applicant has failed to rebut prima facie showing of inherency or obviousness absent objective evidence such as side-by-side testing that would address the ability of the prior art HRV receptors ability to bind LFA-1/Mac-1/p150,95. See Ex parte Raske, 28 USPQ2d 1304 (BPAI 1993).

Even if there is an indication that there may be reduced binding of a particular radiolabeled HRV receptor preparation reduced binding to HRV; it maintained the ability to bind.

It is clear that the Tomassini thesis as well as the other references clearly teach that the HRV receptor is indeed the receptor for rhinovirus, that the HRV receptor is bound by antibodies that block HRV attachment or binding, and that the HRV receptor can be used as an immunogen to produce an antibody that blocks HRV attachment and binding.

Either it was inherent or expected at the time the invention was made that the HRV receptor identified and characterized by the references had the ability to bind virus and, in turn, would have either the inherent or expected properties of binding LFA-1/Mac-1/ p150,95.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112-2113, including 2112.01.

Also, see Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

For example, Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) states: "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144.
While the LFA-1/Mac-1/p150,95 binding of the HRV receptor was not disclosed; the prior art need not disclose a newly discovered property in order for a prima facie case of obviousness. If the claimed and the structurally similar prior art species share a useful property, this will generally be sufficient to motivate an ordinary artisan to make the claimed species. See MPEP 2144.06 , including MPEP 2144.06 4(d).

Therefore, the prior art did not need to rely upon the binding of LFA-1/Mac-1/p150,95, as currently claimed. Clearly, the prior art teaching of the HRV receptor would have either the inherent or expected properties of binding LFA-1/Mac-1/p150,95; given its ability to bind HRV.

With respect to the recitation of "artificial" does not appear; the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Applicant's arguments are not found persuasive.

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 20, 2001